510(k) SUMMARY

McKesson Israel Ltd.'s Horizon Cardiology™ ECG Management

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Date Prepared: 15 November 2011

Name of the device	Horizon Cardiology™ ECG Management
Common Name:	Programmable diagnostic computer
Classification Name:	Computer, Diagnostic, Programmable, 21 C.F.R. § 870.1425
Product code:	DQK
Device Class:	Class II
Predicate Device:	Medcon Ltd., Horizon Cardiology ECG (K061905), GE Healthcare, GE MUSE® Cardiology Information System (K110132)

Intended Use / Indications for Use

Horizon Cardiology™ ECG Management is a software application designed to import, display, store, analyze, distribute and manage information related to ECG procedures of adult and pediatric patients from external ECG devices.

Horizon Cardiology™ ECG Management allows analysis or reanalysis of resting ECGs and provides preliminary data for editing and confirmation by an over-reading physician. Horizon Cardiology ECG Management can also provide a serial comparison of resting ECG data to facilitate review of a patient's current ECG with previous ECGs of the same patient.

Horizon Cardiology™ ECG Management is intended to be used under the direct supervision of a licensed healthcare practitioner and by trained operators in a hospital or facility providing patient care. Horizon Cardiology ECG Management is not intended for real-time monitoring.

Technological Characteristics

Horizon Cardiology™ ECG Management is a standard ECG management system for importing ECG waveform data, reviewing, performing measurements, diagnosis and comparison of ECG procedures and storing them for future review and management.

Horizon Cardiology™ ECG Management functions as a non-real time system. It receives ECG procedure files after the cessation of the ECG procedure, which can originate from any one of a variety of manufacturer's cardiographs, Stress ECG machines, Holter recording devices or Holter analysis and review stations. Horizon Cardiology™ ECG Management acquires the ECG waveforms through a network connection or via a diskette, and normalizes them to a common format. If the ECG cart has made an ECG procedure analysis, Horizon Cardiology™ ECG Management presents it and utilizes the Glasgow University Interpretive Algorithm to perform its own measurements, diagnosis and serial comparison without changing the raw waveform data.

Horizon Cardiology™ ECG Management acquires the Stress and Holter ECG files in PDF format through a network connection, modem or via a portable media (diskette, SD card, etc.) or wireless device and stores them in their original format without changing the file.

Horizon Cardiology™ ECG Management uses an intuitive interface, which provides tools to edit measurements and procedure diagnoses and enables the physician to seamlessly review numerous ECG procedures. Horizon Cardiology™ ECG Management complies with HL7 standards for export to the Hospital Information System (HIS) to provide billing information. Horizon Cardiology™ ECG Management supports final ECG report distribution by printing, faxing, e-mailing and automatic export to other systems. The Horizon Cardiology™ ECG Management database complies with the requirements of HIPAA through robust password security, record access security and file allocation in a secure and managed server.

Horizon Cardiology™ ECG Management allows access to ECG records from web-enabled PC's throughout a network and enables authorized clinical users to access the system from remote locations.

Performance Data

Verification and validation testing was performed on Horizon Cardiology™ ECG Management to ensure it met all specifications. The device was further validated to ensure that it performs as intended. In all instances, Horizon Cardiology™ ECG Management functioned as intended and the results observed demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

Horizon Cardiology™ ECG Management is substantially equivalent to Medcon Ltd.'s Horizon Cardiology ECG (K061905), as well as GE Medical Systems Information Technologies, Inc.'s MUSE® Cardiology Information System (K110132). Horizon Cardiology™ ECG Management has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. All of the products are generally intended to perform the necessary functions required for import, storage, archival, review, analysis, quantification, reporting and database management of cardiology data and reports. In addition, the products have very similar indications for use.

The products also feature identical or very similar Client and Server operating systems, industry standards for system and network connectivity and communication (LAN, WAN, TCP/IP), image communication (DatamedFT™, DICOM), data exchange (HL7 and PDF), file storage and management (disk based and SAN/NAS), and database engines. Moreover, all of the products feature structured templates for reporting on selected types of imaging. The minor technological differences between Horizon Cardiology™ ECG Management and its predicate devices raise no new issues of safety or effectiveness. Thus, Horizon Cardiology™ ECG Management is substantially equivalent to previously-cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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McKesson Israel Ltd.
c/o Mr. Tomer Levy
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Re: K113515
Trade Name: Horizon Cardiology ECG Management
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: February 27, 2012
Received: February 27, 2012

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113515

Device Name: Horizon Cardiology™ ECG Management

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113515